



Florida Department of Agriculture & Consumer Services
CHARLES H. BRONSON, Commissioner

Please Respond to:

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Dockets Management Branch (FA-305)
Food & Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Ref: Docket no. 1916P-0418, 1997P-0197, 1998P-0203 and 2000N-0504
RIN 0910-AC14

I hereby submit this response to FDA proposed rules to improve farm-to-table shell egg safety.

The Florida Department of Agriculture & Consumer Services has a dual mission: 1. To safeguard the public, and 2. To support Florida's agricultural economy. In keeping with both parts of that mission we hereby respectfully submit our comments concerning the above referenced proposed rule.

The last paragraph of II, A, 3. notes that the incidence of S.e cases declines steadily 1990 through 1995 (10,406 cases), 1996 through 2001 (3,913 cases) to 32 outbreaks in 2002, though how many individuals were involved was not included in the report. The paragraph concludes with a statement that much progress has been made through voluntary Q.A. programs, consumer education and nationwide refrigeration requirements; and then concludes that "progress in reducing the number of illnesses and outbreaks appears to have greatly slowed or stopped", hence the need for the regulation. The report up to that point and in the data it contains does not support the assertion that progress has in any way diminished. Yet, we completely agree with proposed regulations that make measures already taken by many producers voluntarily, mandatory for all producers; measures such as pest control, refrigeration, cleaning and disinfection of poultry houses and environmental testing for S.e. inasmuch as those practices are cited in the report as being most responsible for the reduction in illnesses thus far. The conclusion of the study seems to be that reduction in S.e. infected eggs has been uniformly distributed throughout all production facilities since voluntary programs have been put in place, while the logical conclusion would be that the reduction was the result of production from plants that have adopted prevention programs and all but eliminated S.e. from their environments. The persistence of some S.e. cases would indicate that some plants have not properly implemented such practices or not adopted them at all.

We have consistently agreed with the need for mandatory refrigeration requirements and the addition of the December 5, 2000 FDA rule that included retailers, restaurants and institutions in order to close the gap in the refrigeration requirements and include all handlers of eggs prior to the end user within the requirement. Florida has adopted the FDA Food Code and enforces rules

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pertaining to safe handling statements on many products including shell eggs. We urge the FDA and other government agencies to continue to educate the consuming public in the safe handling of eggs and other potentially hazardous foods as we agree with FDA that it has, as the report indicates, contributed greatly to the reduction in cases of S.e. illness.

An area of concern to us is section III, G, sampling and testing. We have long before this time discarded the idea that defects can be sampled out of a product and are somewhat surprised to find the heavy reliance on sampling in the rule. We do not dispute your conclusions in an ideal environment but also know that neither FDA nor our agency will have the means to oversee the process to the extent that we can be assured that every step of the procedure will be followed as designed. We do not have the resources to devote to supervising such an extensive activity, nor does FDA, so we are further skeptical that the expected benefits will result from the rule. Further, Florida has only one small egg products production plant and no egg pasteurization facility at all; it is not likely that alternative use would be made of eggs from flocks identified as S.e. positive. We urge FDA to revise the proposed rule to reduce sampling and testing requirements to dimensions commensurate with the contribution such sampling and testing would make to the reduction of S.e. illnesses, namely, the best of voluntary programs already in place.

We appreciate the opportunity to offer comment on the proposed rule and thank you for any consideration given to our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Bernhardt", with a stylized, cursive script.

Michael A. Bernhardt
Sanitation & Safety Administrator
Division of Food Safety